



22 June 2015

Return Receipt Requested

URGENT: Field Safety Corrective Action

3M™ ESPE™ Lava™ Ultimate CAD/CAM Restorative

Attention: Dentists, Milling Centers and Other Dental Professionals

Affected Product/Lot: 3M ESPE Lava Ultimate CAD/CAM Restorative – All Lots and Catalogue Numbers

Corrective Action:

3M ESPE is voluntarily removing the crown indication from the list of indications for use of Lava Ultimate materials.

Reason for Field Correction:

3M is taking this action consistent with its commitment to provide high quality products to dental professionals and their patients. Approximately 10% of dental accounts have reported to 3M that Lava Ultimate crowns debonded at a rate higher than their typical experience for crowns. The reported debond rates varied greatly and often significantly exceeded the 2-4% rates generally reported in clinical literature. Based on this customer feedback, the product is not meeting performance expectations for consistent and predictable outcomes for the crown indication.

Potential Patient Impact:

Health risks associated with crown debonding have been determined to be low in severity and occurrence. There is no need to contact patients with existing Lava Ultimate restorations or to take additional action beyond normal patient care.

Continued Use for Inlay, Onlay and Veneer Indications:

Lava Ultimate materials are still indicated and can be used for inlays, onlays (with internal retentive elements) and veneer restorations, in accordance with the enclosed updated Instructions for Use (IFU). Clinical and customer feedback support continued use.

Action Required:

3M ESPE Dental

- We ask that you confirm your receipt of the new IFU: please complete the enclosed Field Correction Acknowledgement Form and return it to your local 3M ESPE Representative, or return by 01509 613253 (fax) or 3mespeuk@mmm.com (email) within 5 days.
- Share this information with all members of your staff and keep the enclosed IFU for future reference.
- Discard all copies of the previous IFU.

If you have questions, please contact your local 3M ESPE dental representative.

We apologise for any inconvenience this may cause and thank you for your attention to this matter.

Jonathan P Young

General Sales and Marketing Manager - 3M ESPE Division